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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/910,485

## Applicant(s)

LYLES, MARK B.

## Examiner

Daniel M Sullivan

## Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 5-17,35-40,42,47 and 55-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47,55-67 and 69 is/are allowed.
- 6) ☐ Claim(s) 5-17,35-40 and 42 is/are rejected.
- 7) ☒ Claim(s) 68 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/25/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Non-Final Office Action is a reply to the amendment and response of 25 November 2003 filed in response to the Non-Final Office Action mailed 25 July 2003. Claims 5-17, 35-40, 42, 47 and 53-69 were considered in the 25 July Office Action. Claims 5, 35, 47 and 66 were amended and claims 53 and 54 were canceled in the 25 November Paper. Claims 5-17, 35-40, 42, 47 and 55-69 are presently pending and under consideration.

#### ***Information Disclosure Statement***

The information disclosure statement filed 25 November 2003 has been considered. As no translation has been submitted, the document has been considered in view of the concise explanation set forth in the English language abstract and insofar as it is understood on its face.

#### ***Response to Amendment***

Rejection of claim 53 is rendered moot by cancellation of the claim.

#### **Claim Objections**

Objection to claims 5, 47, 65, 66, 67 and 69 because of minor informalities is withdrawn.

#### **Claim Rejections - 35 USC § 112**

Rejection of claims 35 and 66 under 35 U.S.C. 112, first paragraph, as containing new matter is withdrawn.

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Claim Rejections - 35 USC § 102

Rejection of claims 47, 55-63, 66 and 69 under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (1996) WO 96/01617 is withdrawn.

*New Grounds*

Claim Objections

Claim 68 is objected to because of the following informalities: The word “comprised” should be in the present tense. Appropriate correction is required.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-17, 35-40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lubowe (1984) U.S. Patent No. 4,474,763 in view of Li (1996) WO 96/01617 (previously made of record).

The instant claims are directed to a method to reduce the absorption of ultraviolet radiation by the skin of a mammal comprising applying a formulation comprising nucleic acids having one or more R-group substitutions; and a compound selected from the group of phenylalanine, tryptophan, tyrosine, keratin, albumin, collagen, elastin, riboflavin and retinoic acid, to the skin of a mammal to reduce the absorption of ultraviolet radiation by the skin of said mammal.

Especially in column 4, lines 53-66, Lubowe teaches a method to reduce absorption of ultraviolet radiation by the skin of a mammal comprising applying a formulation comprising a sunscreen and elastin (see throughout) and/or collagen (see especially column 4, lines 40-41). Lubowe contemplates using a variety of chemical sunscreen agents in the formulation but does not teach that the formulation should comprise nucleic acids having one or more R-group substitutions (see the Office Action mailed 3 June 2002, page 3, paragraph 3).

As discussed in previous Office Actions, Li teaches a sunscreen formulation comprising nucleic acids, which, because said nucleic acids are extracted from natural sources, comprise one or more R-group substitutions including methylation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the formulation used in the method of Lubowe to substitute the nucleic acids taught by Li for the chemical sunscreen agents taught by Lubowe according to the instant claimed method. Strong motivation to combine these teachings can be found in Li. In the

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discussion beginning in the first full paragraph on page 4 and continued through the third paragraph on page 6, Li teaches, "since chemical sunscreens are non-natural molecules, their molecular structures are quite different from the nucleic acid molecules which are the direct target for ultraviolet light induced damage to living organisms...due to the lack of understanding of the photochemistry of nucleic acids, whether or not chemical sunscreens protect living organisms from skin cancer is still an unresolved controversy...Further, the radiation that is blocked out by known chemical sunscreens often includes frequencies of sunlight that are beneficial to the body such as the wavelengths of ultraviolet light that are necessary for the body to produce vitamin D" and "synthetic procedures for producing UV-absorbing chemicals may introduce contaminants into the preparation, some of which may be carcinogenic...Chemical sunscreens may mutate on exposure to sunlight, the mutagen being carcinogenic. Indeed, studies suggest that chemical sunscreens might encourage rather than prevent sunlight-related cancers." Thus, the art at the time the invention was made teaches a method of reducing absorption of ultraviolet radiation by the skin of a mammal, teaches all of the components of the formulation of the claims and provides motivation to combine these components as described in the instant application. Furthermore, absent evidence to the contrary, one would have a reasonable expectation of success in combining the teachings of Lubowe and Li because the skilled artisan would expect that the nucleic acids of Li would function in any pharmaceutically acceptable formulation such as the formulation of Lubowe. Therefore, the invention of the base claim 5 as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

The combined teachings of Lubowe and Li also render obvious the alternative formulations set forth in claim 5 and the limitations of the dependent claims 6-17, 35-40 and 42. First, as Li teaches that the sunscreen composition comprising nucleic acids may also contain other ultraviolet absorbing chemicals to provide protection against sunburn (page 10, first full paragraph) the inclusion of UV absorbing aromatic compounds such as phenylalanine, tryptophan, tyrosine, riboflavin, retinoic acid, keratin and albumin would be obvious to one of ordinary skill.

Li teaches that the nucleic acids can be DNA according to claim 5 comprising an average size of at least about 100 base pairs according to claim 6 (see, e.g., the first full paragraph on page 12 and the paragraph bridging pages 12-13) which protect from UVB radiation according to claim 8. In the first full paragraph on page 9, Li teaches that the amount of nucleic acid needed to provide the desired protection can be readily determined by standard methods of testing. Thus, the method of providing the various levels of protection set forth in claims 9-15 would be obvious to one of ordinary skill in the art.

Both Lubowe and Li teach that the method can be used to reduce ultraviolet radiation by the skin of an animal or human, which renders obvious the human, dog and cat of claims 16 and 17.

The DNA of Li is methylated according to claim 35 (*Id.*) and, because the DNA is treated with DNaseI (first full paragraph on page 12 and the paragraph bridging pages 12-13), would comprise nucleic acids less than 100 base pairs according to claim 36. Li teaches that the nucleic acids can be comprised in the composition at an effective concentration which can be determined experimentally and thus renders obvious nucleic acids in a cholesteric liquid phase, a lyotropic

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liquid crystal phase or a precholesteric phase as set forth in claim 37. Furthermore, the nucleic acids prepared according to the method of Li (Examples 1 (A)-(D)) would comprise a complex mixture of nucleic acids, which would comprise single, double or triple stranded DNA according to claim 38 and apurinic acids, purines and uric acids of claim 39. Both Li and Lubowe teach the compositions can comprise the various components set forth in claim 40 (see especially Lubowe, columns 3 and 4, and Li, the paragraph bridging pages 9-10). Finally, Li teaches a DNA formulation comprising a Tris buffer (see especially the section entitled "DNA-containing Cream" beginning on page 15), and buffers such as phosphate and HEPES buffers are commonly used with DNA. Thus, buffers of claim 42 would be obvious to one of ordinary skill in the art.

As the Lubowe and Li teach or suggest all of the limitations of the instant claims and provide motivation to combining the teachings therein according to the instant claimed invention, the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

#### ***Allowable Subject Matter***

Claims 47, 55-67 and 69 are allowed.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Friday 8-4:30.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

*Anne-Marie Falk*  
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PRIMARY EXAMINER